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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/558,628	07/13/2006	Ramiro Martinez-Gutierrez	10451.204-US	4622
25908 7590 12/18/2006 NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110			EXAMINER UNDERDAHL, THANE E	
			ART UNIT	PAPER NUMBER.
			1651	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/18/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/558,628	Applicant(s) MARTINEZ-GUTIERREZ ET AL.	
	Examiner Thane Underdahl	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/30/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

The examiner objects to the characters in front of the Celsius symbols. Please make the appropriate correction.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-17, 21, 23 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 use the term "pre-saccharification" which is queried. Its definition is unclear in the specification. Clarification is required.

Regarding claims 15-17 and 21 contain the phrase "for example" or "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Clarification is required.

Claims 23 and 24 give multiple temperature ranges and time ranges. It is unclear to the examiner which range is the actual limitation in the claim. In the interest of compact prosecution, the examiner will examine the broadest temperature range and time range in each claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaRoye et al. (WO 97/42301) in view of Antrim (U.S. Patent # 5,180,669, 1993) and Wang (Cellulose Degradation, 2001) with support from Thompson et al. (U.S. Patent # 6,468,355, 2002).

These claims are drawn to a method for producing ethanol comprising the following:

- a. providing a mash comprising a starch containing material and water;
- b. preliquefying the mash of step (a) in the presence of a β -glucanase;
- c. gelatinizing the mash of step (b) by jet cooking;
- d. liquefying the mash of step (c) in the presence of an α -amylase, a β -glucanase and a xylanase; and
- e. saccharifying and fermenting the mash of step (d) to produce ethanol.
- f. recovering the ethanol.

LaRoye et al. teach a method of liquefying a mash from cereal grains using a mixture of enzymes including β -glucanase, α -amylase and endo-xylanase (see abstract) for a fermentation process to produce ethanol using yeast (page 2, lines 34-36). They also

Art Unit: 1651

teach their β -glucanase is derived from *Bacillus*, their xylanase from *Aspergillus*. They also teach that suitable materials for their invention are high starch cereal grains such as barley, sorghum, corn and wheat (page 3, lines 28-33). They also teach the use of proteases to liquefy and saccharify their mash. While LaRoya et al. does not teach the use of tubers. However it would be obvious to one of ordinary skill in the art to substitute any of these substrate into the mash for a fermentation process since they contain high amounts starch which can be fermented into ethanol. This is supported by Thompson et al.who teach that the grains listed above as well as potato, sweet potato, cassava, and sago also have a high starch content (col 5, lines 1-5) and are susceptible to fermentation (col 1, lines 48-55). They also teach that their liquefaction step which includes β -glucanase is performed at a temperature about 65 °C from 30 minutes to 2 hours (page 3 line 33 to page 4 line 15). While LaRoya does not specifically teach a "pre-saccharification step" however LaRoya does teach the addition of β -glucanase and cellulases which inherently reduce cellulose to glucose and thus "pre-saccharify" the mash before the saccharification step (page 3, lines 37-40).

What LaRoyle does not teach is a step to gelatinize the mash via jet cooking. However LaRoyle teach that liquefaction steps may be improved by the teachings contained in the patent by Antrim. Antrim et al. like LaRoyle teach the use of α -amylase to improve the liquefaction of starch. Antrim teach jet cooking the starch as a treatment for liquefaction (Antrim, col 4, Example 2). One of ordinary skill in the art would recognize that steam treatment of starch will gelatinize the mash and make it more susceptible to enzymatic digestion to glucose. One of ordinary skill in the art

would be motivated by the fact that improved susceptibility of the substrate to enzymatic digestion to glucose and will improve the over yield of the end product (ethanol) and reduce the reaction time. Additional motivation is provided by LaRoyle who references the work by Antrim in their process to produce ethanol from a substrate mash. The reasonable expectation of success is provided by LaRoyle who successfully ferments ethanol from a mash of cereal grains.

While both of the above references teach some type of pretreatment of to the mash LaRoyle et al. teach the addition of a cellulases, β -glucanase, and α -amylase to hydrolyze the cellulose and start to make it more amorphous to improve enzyme access to the substrate. Antrim teach an acid hydrolysis process to make the substrate more amorphous. However neither specifically teach a pretreatment of β -glucanase in the mash before jet-cooking. This is taught by Wang (Cellulose Degradation). Wang teach that adding β -glucanase degrades the cellulose to make it more amorphous and thus more accessible to enzymatic digestion (page 2 paragraph 1-3). Wang also teach an acid hydrolysis procedure that is similar to Antrim that uses headed acid to hydrolyze the cellulose and make it more amorphous. Therefore it would be obvious to one of ordinary skill in the art to substitute an enzymatic hydrolysis step for an acid hydrolysis step for preliquification of the substrate before jet cooking. Both methods achieve the same result by breaking down the cellulose so that the starch is more accessible to enzymatic degradation to glucose and as such are obvious equivalents (M.P.E.P. § 2144.06) according to Wang.

While Wang teach the enzyme hydrolysis at 40 °C for 24 hours which do not meet the limitations of claim 23. However, M.P.E.P. § 2144.05 II states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the temperature and duration of claim 23 it would be *prima facie* obvious that one of ordinary skill in the art would recognize these limitations are result effective variables whose duration and magnitude are a matter of routine optimization.

Also, to strengthen the obviousness argument, the examiner would point out that during the liquefaction step of LaRoye et al., which uses β -glucanase, the temperature is maintained between 40-60 °C for 30 minutes to 2 hours. Considering that β -glucanase is used in both process it would be obvious to one of ordinary skill in the art to use the conditions of LaRoye in the preliquifaction step as well.

It would have been obvious to someone skilled in the art to take the step of β -glucanase liquefaction as proposed by Wang and add it to the combined method of LaRoyle et al. and Antrim. Since Wang establishes that enzymatic hydrolysis is an obvious equivalent to acid hydrolysis to achieve an amorphous cellulose substrate that will improve enzyme accessibility to digest the substrate thus making the process overall more productive.

Therefore the references listed above renders obvious claims 13-16 and 18-24.

Claims 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaRoye et al., Antrim, and Wang with support from Thompson et al. as applied to claim 13-16, 18-20 and 22-24 above, and further in view of Kleman-Leyer et al. (Applied and Environmental Microbiology, 1996).

These claims further limit claim 13 by adding a endoglucanase derived from Trichoderma. Claim 21 limits claim 13 by requiring the method use a micro-organism.

Claim 13 was discussed in the rejection above. While LaRoye et al., Antrim, and Wang render obvious claim 13 they do not specifically teach the use of endogluconase to the liquefaction step. However endogluconase is a cellulase as taught by Wang, which hydrolyzes the internal bonds of cellulose to make it more amorphous (page 2, paragraph 1) and LaRoyle teach the addition of cellulases to their liquefaction step. In addition Kleman-Leyer et al. teach that endogluconase increases the solubility of cellulose which is the primary goal of liquefaction (see abstract). Therefore it would have been obvious to someone skilled in the art to add endogluconase to the liquefaction step of combined method of LaRoye et al., Antrim, and Wang et al. The motivation and reasonable expectation of success is provided by Kleman-Leyer et al. who teach that endoglucanases are capable of solubilizing cellulose.

Therefore the references listed above renders obvious claim 17.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for

Art Unit: 1651

interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached during regular business hours, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

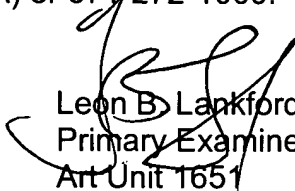
Application/Control Number: 10/558,628

Page 9

Art Unit: 1651

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Art Unit 1651



Leon B. Lankford Jr
Primary Examiner
Art Unit 1651